


REMARKS



Election/Restriction

In view of the final restriction requirement, claims 33-51 have been canceled.

Double Patenting Rejections



The Patent Office rejected claims 16, 18, 19, and 21-23 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,303,572. The Office also rejected claims 21-23 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,290,767 and claims 1-18 of U.S. Patent No. 6,468,964. The Applicants respectfully submit that the rejections are moot in view of the attached Terminal Disclaimer.

Support for the Claim Amendments

Claims 1 and 9 have been amended to recite a vaccine comprising "at least one isolated microorganism or living or dead cells thereof". Support for this amendment can be found at page 4, lines 23-35, and thus does not add new matter.

Claims 1 and 9 have been amended to recite that the vaccine (claim 1) and the pharmaceutical composition (claim 9) are "effective for the prevention of lactic acidosis in said monogastric, herbivore, or ruminant animal." These claim amendments are supported by claims 1 and 9 as originally filed, and claim 4 as originally filed and thus do not add new matter.

Claims 1 and 9 have been further amended to incorporate the "monogastric, herbivore or ruminant animal" limitation from claim 4 into claims 1 and 9. As this limitation was present in originally filed claim 4, these amendments do not add new matter.

Claims 1, 2, 9 and 10 have been amended to recite particular species and/or strains of *Bacteroides*, *Selenomonas* and *Streptococcus* microorganisms. These claim amendments are supported by claims 3 and 11 as originally filed and thus do not add new matter.

Claims 2-3, 10-11, 22-23 and 52 have been amended to add indications for the strain designations and Accession numbers. Support for these amendments can be found at page 2, line 32-page 4, line 5, and thus these amendments do not add new matter.

Claims 3, 11, 23 and 52 have been amended to correct the genus of bacteria to which strain LAB05 belongs. Support for this amendment can be found at page 3, lines 24-26, and thus these amendments do not add new matter.

Claim 20 has been amended to incorporate the specific active agents originally claimed in claim 25. Thus, this amendment does not add new matter.

The following claims have been amended to correct typographical errors: 1, 3, 11, 23 and 52. These amendments do not add new matter.

Claim Objections

Paragraph 9

Claim 24 is objected to for improper form. Claim 24 has been canceled, rendering this objection moot.

Paragraph 11

Claim 4 is objected to for being written in improper dependent form. Claim 4 has been canceled, rendering the objection moot as to that claim.

Paragraph 12

Claim 5 is objected to for being written in improper dependent form for broadening the scope of the claim from which it depends. In view of the amendments to claims 1 and 5, it is submitted that this objection is now moot. Claim 1 has been amended to clarify that the microorganisms which are capable of producing lactic acid are living microorganisms. Furthermore, claim 5 has been amended to limit the dead cells to "intact cells." In light of these amendments to claims 1 and 5, it is submitted that claim 5 is now in proper dependent form.

Paragraph 13

Claim 9 is objected to for an improper Markush group. As suggested by the Examiner, claim 9 has been amended to rearrange the elements so that the "pharmaceutically acceptable carrier, adjuvant and/or diluent" elements are recited before the Markush group, thereby clarifying the Markush group.

Paragraph 14

Claim 12 is objected to for broadening the scope of the claim from which it depends. In view of the amendments to claim 9, it is submitted that this objection is now moot. Claim 9 has been amended to clarify that the microorganisms which are capable of producing lactic acid are living microorganisms. In light of this amendment to claim 9, it is submitted that claim 12 is within the scope of claim 9.

Paragraph 15

Claim 13 is objected to for broadening the scope of the claim from which it depends. This objection is now moot in view of the cancellation of claim 13.

Paragraph 16

Claims 26-28 and 30 are objected to for a number of informalities. These objections are now moot in view of the cancellation of claims 26-28 and 30.

Claim Rejections 35 U.S.C. § 112

Paragraph 18

Claims 2-3, 10-11, 22-23 and 52 are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement for the specific bacterial isolates. The applicants respectfully traverse. All of the deposit requirements recited by the Examiner on p. 7 of the Office Action are met by the disclosure on pp. 2 and 3 of the specification. Therefore, the applicants respectfully request withdrawal of this rejection.

Paragraph 19

Claims 1-23 and ~~25-32~~ are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement and written description for any fragment or fragments of any of the recited microorganisms. Claims 4, 6, 7, 13, 14 and 25-32 have been canceled, rendering the rejection moot as to those claims. As to the remaining claims, independent claims 1 and 9 have been amended to remove the "fragment or fragments" limitation, thereby obviating these rejections as to the remaining claims.

Paragraph 22

Claims 1-23, 25-32 and 52 are rejected for indefiniteness under 35 U.S.C. § 112, second paragraph for allegedly claiming microorganisms that may in fact cause lactic acidosis. Claims 4, 6, 7, 13, 14 and 25-32 have been canceled, rendering the rejection moot as to those claims. The Examiner has alleged that the vaccine of the present invention may in fact cause lactic acidosis as opposed to preventing it in view of the ability of the microorganisms recited to produce lactic acid. However, the lactic acid producing bacteria only produce lactic acid in the presence of an abundant amount of fermentable carbohydrate. No such carbohydrate is present in the vaccine formulations/pharmaceutical compositions of the invention. As such, the microorganisms of the vaccine by themselves cannot cause lactic acidosis. Based on this clarification, the applicants respectfully request withdrawal of this ground of rejection.

Paragraph 23

Claims 1-23, 25-32 and 52 are rejected for indefiniteness under 35 U.S.C. § 112, second paragraph for reciting a "fragment or fragments." Claims 4, 6, 7, 13, 14 and 25-32 have been canceled, rendering the rejection moot as to those claims. This rejection is inappropriate as to claim 52 as this claim does not recite "fragments." As to the remaining claims, independent claims 1 and 9 have been amended to remove the "fragment or fragments" language. Therefore, applicants respectfully request withdrawal of this ground of rejection as to the remaining claims.

Paragraph 24

Claims 1-23, 25-32 and 52 are rejected for indefiniteness under 35 U.S.C. § 112, second paragraph for reciting the term "like." Claims 4, 6, 7, 13, 14 and 25-32 have been canceled, rendering the rejection moot as to those claims. The term "like" has been removed from all the remaining claims. Therefore, this rejection is also moot as to claims 1-3, 5, 8-12, 14-23 and 52.

Paragraph 25

Claims 3, 11, 23 and 52 are rejected for indefiniteness under 35 U.S.C. § 112, second paragraph for reciting information in parentheses. To clarify the meaning of the abbreviations in parentheses, the term "strain:" has been inserted in the first parentheses and "accession number:" in the second parentheses.

Regarding the Examiner's rejection of claim 6, in view of the cancellation of claim 6, this rejection is now moot.

Paragraph 27

Claims 7 and 14 have been canceled, rendering this rejection moot.

Paragraph 28

Claim 13 is rejected for indefiniteness under 35 U.S.C. § 112, second paragraph for not clearly redefining a term. This objection is now moot in view of the cancellation of claim 13.

Paragraph 29


Claims 20-23 are rejected for indefiniteness under 35 U.S.C. § 112, second paragraph for reciting "an active agent." Claim 20 has been amended to recite the specific active agents originally listed in claim 25. Claim 21 (and the claims 22 and 23 which depend from claim 21) has been amended to no longer recite "an active agent."

Paragraphs 30 to 35

These rejections are now moot as claims 25 to 32 have been canceled.

Claim Rejections - 35 USC § 102

The Examiner has alleged that the following documents deprive various claims of novelty:

- (i) WO97/14802 162b
 - (ii) WO99/00136 102b
 - (iii) US 4,906,612
 - (iv) US 5,380,525
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The applicants respectfully disagree and provide the following comments:

WO97/14802 (Leer et al.)

Claims 1-4 and 6-14 are rejected as anticipated by Leer et al. Claims 4, 6, 7, 13 and 14 have been canceled, rendering the rejection moot as to those claims. The basis for the rejection is that Leer et al. describes a protein from *Lactobacillus fermentum* that is purportedly useful for combating *Clostridium* infection and, therefore, such a protein comprises a fragment of a *Clostridium*-like species (see first two paragraphs on p. 15 of the Office Action). The applicants respectfully traverse. Leer et al. teaches that an adhesion protein from *L. fermentum* binds to the mucosa and thereby interferes with binding to the mucosa and thereby prevents infection by microorganisms, e.g., *Clostridium*, that specifically bind to mucosa receptors. See p. 10, ll. 5-23 of Leer et al. This does not make *L. fermentum* a *Clostridium*-like microorganism or an adhesion protein from *L. fermentum* a fragment of a *Clostridium*-like microorganism any more than, for example, the antibiotic metronidazole (effective against *Clostridium difficile*) is a fragment of a *Clostridium*-like microorganism. On this basis alone Leer et al. does not anticipate the claims. Furthermore, the claims have been amended to remove the modifier "like", which also obviates this rejection. In view of the foregoing, the applicants respectfully request reconsideration and withdrawal of this rejection.

WO99/00136 (Rowe)

Claims 1-23, 25-32 and 52 are rejected as anticipated by Rowe. Claims 4, 6, 7, 13, 14 and 25-32 have been canceled, rendering the rejection moot as to these claims. The basis for the rejection is that Rowe teaches the use of whole living cells to treat or prevent the accumulation of acid in the gastrointestinal tract. The applicants respectfully submit that in light of the amendments to claims 1, 2, 9 and 10 to recite particular species and/or strains of *Bacteroides*, *Selenomonas* and *Streptococcus* microorganisms, Rowe cannot anticipate the remaining claims. Rowe teaches the use of bacteria from the genus *Bacteroides* or *Selenomonas* (see claim 14) or *Streptococcus bovis* (see p. 11, lines 5-8) to treat or prevent the accumulation of acid in the gastrointestinal tract. Thus, Rowe merely discloses a genus of compositions (that being several genera of microorganisms) that can be used. It is settled that a genus does not necessarily anticipate a species. See *In re Kollman*, 201 USPQ 193 (CCPA 1979). Since Rowe does not teach the particular species and/or strains of *Bacteroides*, *Selenomonas* and *Streptococcus* microorganisms in amended claims 1, 2, 9 and 10, or in claim 52, Rowe cannot anticipate the remaining claims. Furthermore, the Examiner alleges that Rowe discloses the use of compositions which comprise *Enterococcus* to treat or prevent the accumulation of acid in the gastrointestinal tract (see the third paragraph of page 15 of the Office Action). However, Rowe merely teaches that a human or animal can be immunized against organisms from the genus *Enterococcus* (see claim 18). Rowe does not teach using bacteria from the genus *Enterococcus* to treat or prevent the accumulation of acid in the gastrointestinal tract. For the foregoing reasons, the applicant requests withdrawal of this rejection.

US 4,906,612 (Hayashi et al.)

Claims 1-4, 7 and 9-14 are rejected as anticipated by Hayashi as evidenced by U.S. Pat. No. 6,429,006. Claims 4, 7, 13 and 14 have been canceled, rendering the rejection moot as to those claims. Hayashi et al. discloses a novel agent which comprises a glycopeptide compound and a salt thereof that have antibacterial activity on strains belonging to the genus *Clostridium*. See col. 1, lines 5-6, col. 2, lines 27-29. However, Hayashi et al. does not disclose an immunogenic glycopeptide from any of the microorganisms recited in claim 1 or the use of such a glycopeptide for the prevention of lactic acidosis, as recited by amended claims 1 and 9. Rather, Hayashi et al. teaches isolation of the glycopeptide from *Nocardia* sp. (see col. 3, l. 56, et seq.). It is therefore

submitted that claims 1 and 9, as well as the claims that depend from them (claims 2-3, 10-12) are novel in light of Hiyashi *et al.*

US 5,380,525 (Leedle *et al.*)

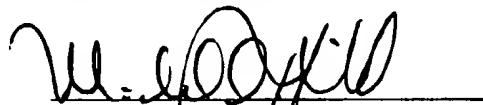
Claims 21-23 are rejected as anticipated by Leedle *et al.* The basis for this rejection is that Leedle *et al.* describes a method for the treatment and/or prophylaxis of lactic acidosis comprising administration of an active agent capable of preventing or controlling lactic acid accumulation. See the first paragraph of page 18 of the Office Action. However, Leedle *et al.* fails to disclose all of the elements of claims amended 21-23. As amended, claim 21 requires that the method comprise the administration of the vaccine of claim 1. The Examiner has not rejected claim 1, as originally filed, as anticipated by Leedle *et al.* Thus, amended claim 21 (and dependent claims 22 and 23) cannot be anticipated by Leedle *et al.*

Conclusion

In view of the foregoing, the applicants respectfully request reconsideration and withdrawal of the objections and §§ 102 and 112 rejections. If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

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Respectfully submitted,


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